
220 W. Market Street
Warsaw, IN 46580
574-268-2252

May 22, 2002

Dockets Management Branch
Division of Management Systems and Policy
Office of Human Resources and Management Services
Food and Drug Administration
5630 Fishers Lane, Room 1061, (HFA-305)
Rockville, MD 20852

**Re: Docket No. 02D-0039**

Symmetry Medical Inc. is making the following comments on the above referenced Docket No. document entitled *Premarket Notification [510(k)] Submissions for Medical Sterilization Packaging Systems in Health Care Facilities; Draft Guidance for Industry and FDA*, which was released for comment on March 7, 2002. Comments are given by page number and paragraph as indicated in the Draft document. Text excerpts are followed by our comments.

**Page 2 – 1st Paragraph**

**Text –** *This guidance includes sterilization trays and cassettes used for sterilization in health care facilities, because they are intended to enclose medical devices for terminal sterilization and they are considered a medical sterilization packaging system. Therefore, they are Class II devices requiring the submission of a premarket notification [510(k)]. On February 18, 1998, the CDRH Office of Compliance sent a letter to the manufacturers..*

**Comment –** The phrase "medical sterilization packaging system" is vague, and has not previously been used to describe any class of medical devices. We do not agree that items such as sterilization trays, mats, and cassettes should be subject to premarket notification. The letter sent to manufacturers cites the Final rule published in The Federal Register, dated October 21, 1980, Vol. 45, No. 202, page 69732 as justification. There is nothing in that Final Rule which implies that sterilization cases, mats, or cassettes were intended to be included as accessories to sterilization wrap. In the text of the Proposed Rule published in The Federal Register, dated



02D-0039

C7

August 24, 1979, Vol. 44, No. 166, page 49945, the reasons for the recommend classification of Sterilization Wrap, by two expert panels are given. Their concerns were strictly limited subjects such as particulates, material permeability, maintenance of sterility, shelf life, and wetting properties.

**Page 2 – 2nd Paragraph, 1st Sentence**

**Text –** *The proper use and adequate performance of medical sterilization packaging systems used in health care facilities is important to prevent nosocomial infections.*

**Comment –** We agree with this statement, but wish to emphasize that proper use and adequate performance is not entirely controlled by manufacturers. Health care facilities have a role in following instructions for use, selecting appropriate equipment, and verifying system capabilities according to good hospital practices. A manufacturer of medical sterilization packaging systems cannot possibly verify all possible combinations of devices, sterilizers, and cycles.

**Page 3 – 2nd Paragraph**

**Text –** *Sterilization Containers, cassettes, trays, etc. intended to be used for sterilization are considered accessories to sterilization wrap...*

**Comment –** With regard to cassettes, trays, etc. we do not believe this is supported or was intended in the regulation. Including everything from silicone mats and wire baskets to sterilization cassettes and trays as accessories to sterilization wrap is not supported by the intent of the regulation in which maintenance of sterility is a key property of the device or accessory.

**Page 6 – 2nd Paragraph**

**Text –** *A medical sterilization wrap or packaging system is a Class II device (product code FRG or KCT) subject to premarket notification 510(k) requirements...*

**Comment –** FDA has not consistently regulated medical sterilization packaging systems as such. As an example, K944025, was cleared under regulation no. 878.4800, product code FSM. We feel this is a more appropriate category for this product. Devices in 878.4800 are now generally exempt from premarket notification.

**Page 7 – 1st Paragraph**

**Text –** *2. The addition of new sizes of sterilization containers to a family of 510(k)-cleared sterilization containers, as long as the configuration and perforations remain the same.*

**Comment** – There is no indication that any "formula" exists, which makes configurations and perforations applicable across size ranges. Surface area of the perforated outside walls decreases, as a ratio to volume inside as you increase the size of a container. (a 5x5x10" container has 250 square inches of surface area and 250 cubic inches of volume, however a 6x6x10" container has 312 square inches of surface area and 360 cubic inches of volume) It would be more appropriate to add sizes within a known minimum and maximum range of sizes for which validation information is available. Adding sizes larger than those previously evaluated may be appropriate for FDA review.

**Page 11 – 4th bullet under 2. Specifications and Tolerances**

**Text –** *Cassettes – design, percentage of open area or perforations, identification of sterilization wrap, mats.*

**Comment** – Validation of sterilant penetration/effectiveness is more relevant than percentage of open area or perforations. As mentioned earlier, the ratio of surface area to volume varies, so a percentage of perforations on the outside of the cassette does is not a constant indicator of what happens inside. Identification of sterilization wrap should be limited to "FDA cleared", wrap. Manufacturers should not have to specify their product for use with a given wrap by supplier/catalog number.

**Page 11 – Item 6.**

**Text –** *Limits of reuse*

**Comment** – This should specify, "if applicable".

**Page 12 – 3rd Paragraph**

**Text –** *Sterilization cassettes and trays are reusable devices, therefore you should provide their limits of reuse.*

**Comment** – Limits of reuse need only be provided if the expected life of the product is less than 500 sterilization cycles.

**Page 12 – 2nd Paragraph from bottom of page**

**Text –** *You should provide validation data for the accessories and the instruments that are to be used with the sterilization packaging system.*

**Comment –** There are many cases in which the manufacturer of the sterilization packaging system cannot possibly know or validate all instrument combinations, which may be used with the system. It is more appropriate for the sterilization packaging system manufacturer to validate using example instruments, and to instruct users to pay particular attention to the instructions given by instrument manufacturers for further sterilization guidance.

**Page 12 – Last Paragraph**

**Text –** *If the new device includes a number of sizes and configurations, the samples selected for obtaining performance information should adequately represent all of the sizes and configurations that will be considered cleared under the 510(k).*

**Comment –** We agree with the text, however it is at odds with the implication earlier at the top of Page 7 (item 2), that new sizes would not require any further review. See our comment on that item.

**Page 13 – 2nd to Last Line**

**Text –** *The information should be in a form that allows for comparison with the predicate in order to determine substantial equivalence.*

**Comment –** As this standard is lumping containers, cassettes and components under on product code (KCT), comparisons to predicate devices may be poor indicators of performance. The key to evaluation of penetration and contact is the use of bioindicators. Comparing a small cassette to a large container (or visa versa), provides no additional assurance of utility.

**Page 14 – Last Line in section 4. Biological Indicators**

**Text –** *The established sterilization cycle time should be within the standardized cycle time of the sterilizers routinely used in the health care setting.*

**Comment –** This is statement is not directly relevant to Biological Indicators. In addition, there are no "standardized" cycle times routinely used in health care settings. There are commonly used cycles, which are

frequently adjustable according to load density and drying time needs. The cycle time recommendations from the manufacturer of the instruments loaded into the tray may not be "standardized", and they must be followed over and above the packaging system suppliers recommendations.

**Page 14 - Section 5. Steam Sterilant**

**Text –** *For steam sterilant penetration testing of containers and cassettes, you should obtain temperature profiles by placing (thermocouple) temperature probes in the chamber, in the container, on the instruments, and near the chamber drain....*

**Comment –** While good information, this is by no means necessary to assess suitability of a steam sterilization process. Thermocouple data does not necessarily give any indication of steam penetration since there is no way to determine if the temperature reading is due to direct steam contact, or convection/conduction heat of metal objects in the load. Biological indicators are the best determinant of adequate steam penetration.

**Page 14 – Section B. Package Integrity, 1. Physical Properties, 1st Line**

**Text –** *You should conduct performance testing to show the physical properties of the material.*

**Comment –** Such additional testing by a manufacturer may not be needed for metal and plastic materials for which there is adequate existing data.

**Page 15 – Section 2. Microbial Barrier Properties, 1st Line**

**Text –** *You should conduct performance testing demonstrating the microbial barrier properties of the medical device packaging system after sterilization.*

**Comment –** This testing is not applicable to manufacturers of cassettes, trays, and accessories. It is the responsibility of wrap and container manufacturers to do this testing.

**Page 17 – Section 5. Sterilization Cassette Integrity, 3rd Line**

**Text -** *No claims can be made for maintenance of sterility unless the cassette is wrapped with sterilization wrap.*

**Comment –** "*or in a sterilization container*" should be added to this sentence.

**Page 17 – Section C. Maintenance of Package Integrity, both Paragraphs**

**Text –** *An important characteristic of a medical sterilization packaging system is its ability to maintain the sterility of the enclosed medical device ...*

**Comment –** This guidance document has lumped cassettes, cases, trays, and accessories together with sterilization containers and sterilization wrap as Medical Sterilization Packaging Systems. It needs to be clear in sections such as Maintenance of Package Integrity, that this does not apply to cassettes, cases, trays, and accessories.

**Page 18 – Section 1. Drying Time, 2nd Line**

**Text –** *Drying time for a steam sterilizer is usually 25 minutes.*

**Comment –** We are not aware of any "usual" standard which applies to all steam sterilizers with all load configurations. What is the basis for this drying time?

**Page 18 – Section 1. Drying Time, 4th Line**

**Text –** *Certain plastic containers require longer than the standard drying time.*

**Comment –** The term *"containers"* may not be appropriate since it is limited to the definition given earlier in the document. As stated above, we are not aware of a *"standard drying time".* Singling out plastic is not appropriate since other types of packaging systems such as those with multiple trays or layers, silicone mats, and poorly designed drainage features may all have longer drying times.

**Page 18 - Section 1. Drying Time, Last Line**

**Text –** *The labeling should state whether the drying time is over 25 minutes; how long the drying time is; and that this drying time is required to prevent wet packs.*

**Comment –** Since several factors such as loading pattern, load density, and steam quality can all contribute to wet packs. A manufacturers label can only provide guidance on drying times. No manufacturer can recommend any reasonable time that will *"prevent"* wet packs since they are not in control of all of the causes.

**Page 18 – Section 3. Plastic Containers – Subject Line and First Sentence**

**Text –** *3. Plastic Containers, A plastic container with a non-woven liner...*

**Comment -** The term "*container*" may not be appropriate since it is limited to the definition given earlier in the document.

**Page 19 – Last Two Lines in First Paragraph**

**Text –** *For reusable packaging systems such as plastic containers, the aeration of EO residuals should be performed after the limits of reuse, because retention build-up of EO residuals in the plastic may affect the container or its contents. Since these containers are reusable, the amount of EO residuals that remain on the container after the limits of reuse may be above the levels otherwise acceptable for single use devices.*

**Comment –** We are not aware that this is a problem. Many systems do not have limits of reuse. Residuals do not add up an accretive fashion since aeration to acceptable limits occurs between each use. It is important to keep in mind that sterilization packaging systems are just packaging. We are not aware that other reusable devices that actually come into contact with patients have ever had to be evaluated in this manner.

**Page 19 – Section E. Additional Information for Reusable Containers and Cassettes, 1st Line**

**Text –** *For reusable containers and cassettes, data should be provided as described in FDA guidance "Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities;...*

**Comment –** According to AAMI TIR No. 12, Reusable containers and cassettes are *Noncritical items*, because they do not ordinarily come into contact with the patient. Cleaning, reprocessing and care instructions are "recommended" but not required for this type of equipment according to the FDA guidance document.

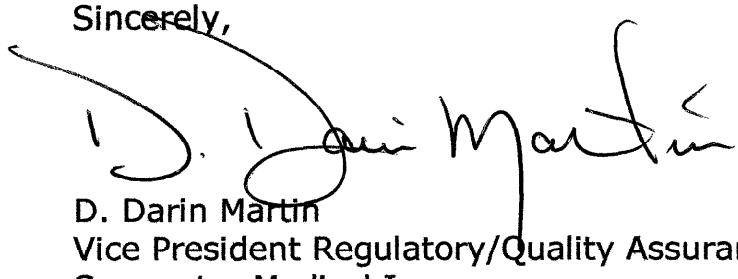
**Page 21 – 8th Bullet from top of page**

**Text –** *Shelf-life*

**Comment** – Shelf life need only be discussed in the labeling when it is relevant. For devices, which can be re-used repeatedly (more than 500 times) there is no need for a shelf life.

Please contact me if there are any questions related to our comments. Symmetry Medical Inc. appreciates the opportunity to respond to this Draft Guidance.

Sincerely,



D. Darin Martin
Vice President Regulatory/Quality Assurance
Symmetry Medical Inc.